UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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THE ORIGINAL CREATINE PATENT COMPANY, LTD.,

Plaintiff,

-against-

MET-RX USA, INC.,

Defendant
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MEMORANDUM & ORDER

Civil Action No. 05-2244 (DRH)(JO)

APPEARANCES:

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HURLEY, Senior District Judge:

Plaintiff The Original Creatine Patent Company, Ltd. ("OCPC") commenced this action accusing defendant MET-Rx USA, Inc. ("MET-Rx") of direct and indirect infringement of two patents in violation of 35 U.S.C. § 271(a)-(b). Presently before the Court are the objections of both parties to the Report and Recommendation of Magistrate Judge James Orenstein regarding claim construction (the "R&R"). For the reason set forth below, both parties' objections are denied and the Court adopts the R&R in its entirety.

Background

I. The Patents in Suit and the Terms at Issue

At issue in this litigation are two patents: U.S. Patent No. 5,767,159 (the "'159 Patent") and U.S. Patent No. 5,968,544 (the "'544 Patent"). Both relate to the use of creatine, also known as methyl guanidine acetic acid, a compound that the human body produces naturally and stores in skeletal muscle, as a dietary supplement. In general, the '159 Patent concerns a method for increasing the body's supply of creatine to improve muscle performance and the '544 Patent concerns a creatine-based composition for human consumption and a method of providing the same. A more detailed description of the patents is set forth below.

A. The '159 Patent

The '159 Patent essentially claims a method for administering creatine so as to increase the creatine content in muscle tissue to improve muscular strength and functioning. ('159 Patent

col.1 ll.4-19.) As creatine was discovered in the nineteenth century, there is a great deal of prior art concerning its administration. The '159 Patent discloses a number of prior patents claiming the use of creatine-related ingredients in both medical and veterinary treatments. The specification differentiates the claimed invention from this prior art principally on the basis that (1) it uses creatine as opposed to creatine-related ingredients such as phosphocreatine and cyclocreatine, and (2) it calls for higher doses than found in the prior art. (*Id*. at col. 2 ll.48-67.) According to the specifications, the claimed invention can be used to improve muscle capacity and functioning in patients suffering from a variety of cardiac and respiratory conditions and to prevent the depletion of creatine during intense physical activity.

At issue is the first claim of the '159 Patent which provides:

> A method for increasing the muscle performing capacity in mammals having no disorder in creatine metabolism but suffering from or running a risk of depletion of muscle phosphoryl creatine storage comprising administering daily to said mammals, either enterally or parenterally, at least 0.2 [grams of] creatine [per kilogram] of body weight and not less than an amount corresponding to 15 [grams of] creatine in a 70[kilogram] mammal.

'159 Patent, col. 6 ll.19-25 ("Claim 1"). More specifically, the dispute concerns the construction of (1) "suffering from or running a risk of depletion of muscle phosphoryl creatine storage" which according to the R&R means "having reduced, or potentially reduced, phosphoryl creatine storage in muscle;" and (2) "not less than an amount corresponding to 15g creatine in a 70 kg mammal" which Judge Orenstein found requires no construction beyond its plain terms. (*See* R&R at 14, 24.)

B. The '544 Patent

The invention claimed in the '544 Patent concerns the human consumption of creatine compositions and a method of providing them so as to preserve their effectiveness. The composition is acidic and can be liquid, semi-liquid or powder. ('544 Patent col.2 ll.16-52.) The method of administration is described as a means of storing the composition in its liquid form or supplying it in a powder form for mixing with water to create an "isotonic drink" defined as a drink that "corresponds to the osmotic potential of human body fluids." (*Id.* col.2 ll.35-37, 53-58 & col.3 ll.10-15.) The invention concerns both the provision of the composition in its powder form, as well as its storage in liquid and semi-liquid form. The disputed term, "unitary doses," concerns the provision of the composition in its powder form and is found in claim 17 which provides: "A composition according to claim 9, provided as unitary doses." (*Id.* col.10 ll.43-44.) Claim 9 states: "A stable, dry powder composition comprising creatine, said composition being unflavored or fruit flavored, which, when mixed with water or an aqueous solution, provides an acidic drink for human consumption, said creatine being substantially stable at ambient temperature or below." (*Id.* col.10 ll.17-21.) In his R&R, Judge Orenstein recommended that the term "unitary doses" be construed to mean "10-20 grams of creatine composition that are individually packaged in sachets, bags, packets, cylinders, bottles, or other suitable packages." (R&R at 26-27.)

II. The Parties' Contentions

MET-Rx objects to Judge Orenstein's recommended construction of the term "not less than an amount corresponding to 15 g creatine in a 70 kg mammal" in claim 1 of the '159 Patent. It contends that the correct construction is "administering said creatine only to mammals of at

least 70 kg body weight, in an amount not less than 15g." MET-Rx maintains that this construction is supported by (1) extrinsic evidence, (2) the prosecution history, (3) the requirement that a claim be definite; and (4) admissions made by the inventor during the prosecution of foreign counterpart patents.

OCPC objects to Judge Orenstein's recommended construction of "suffering from or running a risk of depletion of muscle creatine storage" in claim 1 of the '159 Patent and of "unitary doses" in claim 17 of the '544 Patent. It maintains that the recommended construction is inconsistent with and ignores the prosecution history of the two patents and erroneously links the two patents and invention. OCPC asserts that the correct construction of "suffering from or running a risk of depletion of muscle creatine storage" should be construed as referring to the depletion of creatine stores that occurs after intensive physical activity. With respect to "unitary doses" it argues that the terms includes unitary doses that are not individually packaged.

Discussion

I. Standard of Review

All portions of the R&R that have been objected to shall be reviewed *de novo*. Fed. R. Civ. P. 72(b); *Thomas E. Hoar, Inc. v. Sara Lee Corp.*, 900 F.2d 522, 525 (2d Cir. 1990).

II. Claim Construction Standard Generally

The construction of patent terms is a question of law determined by the court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 983-84 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 372 (1996). A court must determine the meaning of disputed claim terms "from the perspective of one of ordinary skill in the pertinent art at the time of filing," and in doing so may rely upon a patent's claim language, specification, prosecution history and extrinsic evidence.

Chamberlain Group, Inc. v. Lear Corp, 516 F.3d 1331, 1335 (Fed. Cir. 2008); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 (Fed. Cir. 2005) (en banc). Due to their enhanced reliability and the fact that they were made in direct contemplation of the invention, the claim language and patent specification are accorded the greatest significance, followed by the prosecution history and extrinsic evidence. *Id*. at 1318-19.

Claims are the focal point of a patent because they "define the invention to which the patentee is entitled the right to exclude." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004). The interpretation of disputed terms begins with the claim language itself and its plain meaning to one of ordinary skill in the art. *Phillips*, 415 F.3d at 1312-13; *see also Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1301 (Fed. Cir. 2006) ("claim construction must begin with the words of the claims themselves"). However, claims do not stand alone; they must be read in light of the accompanying specification and claim terms should "normally" be used consistently throughout the patent. *Markman*, 52 F.3d at 979; *Phillips*, 415 F.3d at 1314.

Although the specification is "the single best guide to the meaning of a disputed term," a court may not import "limitations into a claim from the written description." *Chamberlain Group, Inc.*, 516 F.3d at 1335; *see also E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988) (holding that it is improper to read a limitation "into a claim from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim"); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (stating that the specification is usually "dispositive[,] . . . the single best guide to the meaning of a disputed term"). Moreover, although a claim is not necessarily limited

to embodiments disclosed in the specification, "repeated and definitive remarks in the written description" can be used to refine claim language. *Computer Docking Sta. Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374 (Fed. Cir. 2008) (citing *Watts v. XL Sys*., 232 F.3d 877, 882 (Fed. Cir. 2000) which states that "repeated and definitive remarks in the written description could restrict a claim limitation to a particular structure"). In fact, when a patentee gives a "special definition . . . to a claim term . . . that differs from the meaning it would otherwise possess . . . " the patentee's "lexicography governs." *Phillips*, 415 F.3d at 1316; *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) ("A claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history."); *Vitronics Corp.*, 90 F.3d at 1582 ("The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.") (citing *Markman*, 52 F.3d at 979); *cf. Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1291 (Fed. Cir. 2008) (stating that if a patent "specification does not reveal any special definition for . . . [a term, it must be construed] according to [its] . . . ordinary meaning"). Moreover, unless an embodiment disclosed in the specification was "clearly" disclaimed or found to be "inconsistent with unambiguous language in the patent's specification or prosecution history," it should usually be included when determining claim scope. *Oatey Co. v. IPS Corp,* 514 F.3d 1271, 1276-77 (Fed. Cir. 2008) (citations omitted); *Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1138-39 (Fed. Cir. 2007); *see also id.* at 1138 (eliminating one of twenty-one "preferred" embodiments disclosed among two patent specifications because it was inconsistent with the unambiguous language of the patent specifications) (citations omitted); *see generally PSN Ill., LLC v. Ivoclar*

Vivadent, Inc., 525 F.3d 1159, 1166 (Fed. Cir. 2008) (limiting *Oatey*, stating: "*Oatey* is not a panacea, requiring all claims to cover all embodiments. . . . Likewise, during prosecution, an applicant may have cancelled pending claims but not amended the specification to delete disclosure relevant only to the cancelled claims.").

In addition to the patent claims and the written description, a court may consult the prosecution history while construing disputed claim terms. *See Phillips*, 415 F.3d at 1317. The prosecution history can "often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution." *Id.* Moreover, "a statement made by the patentee during [the] prosecution history of a patent in the same family as the patent-in-suit can" further elucidate disputed claim language or "operate as a disclaimer." *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1306 (Fed. Cir. 2007) (citing *Microsoft Corp. v. Multi-tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004)). However, since the prosecution history merely represents "an ongoing negotiation between the [United States Patent and Trademark Office] . . . and the applicant," it "often lacks the clarity [and probative value] of the specification." *Phillips*, 415 F.3d at 1317.

Although a court should attach greater value to intrinsic evidence, which includes the patent's claims, written description and prosecution history, it may also use extrinsic evidence to interpret disputed claim language. "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman,* 52 F.3d at 980. It can be used to inform the court of the technology, background and nuances related to the disputed claim terms. *Phillips*, 415 F.3d at 1318;

Vitronics, 90 F.3d at 1644. However, extrinsic evidence is often flawed because it: (1) is not contemporaneous with the patent; (2) may not reflect the understanding of one skilled in the art; or (3) may be biased or generated for the purpose of litigation. *See Phillips*, 415 F.3d at 1318. In fact, "expert testimony at odds with the intrinsic evidence must be disregarded." *Network Commerce, Inc. v. Microsoft Corp.*, 422 F.3d 1353, 1361 (Fed. Cir. 2005) (citing *Phillips*, 415 F.3d at 1318).

III. Claim 1 of the '159

As noted above, the parties have filed objections relating to two clauses in claim 1 of the '159 Patent. The Court shall first address the construction of "suffering or running a risk of depletion of muscle phosphoryl creatine storage." It will then proceed to construe "not less than an amount corresponding to 15g creatine in a 70 kg mammal."

A. "[S]uffering or running a risk of depletion of muscle phosphoryl creatine storage"

OCPC maintains that the appropriate construction of the term "suffering or running a risk of depletion of muscle phosphoryl creatine storage" is much narrower than recommended by Judge Orenstein and should be limited to a depletion of creatine that occurs after intense physical exercise. In view of the fact that the patent specifications identify numerous uses for creatine, uses which are not limited to addressing the results of "intense physical activity," the Court rejects OCPC's attempt to narrow the language of the claim.

The specifications of the "159 Patent provides in relevant part:

> Thus, nothing is disclosed or suggested in the above-mentioned prior documents which would lead a man skilled in the art to the findings that the supply of a daily dose of at least 15 g of creatine or 0.2-0.4 g/kg body weight or preferably about 0.3 g/kg body

> weight administered orally, enterally or parenterally to a mammal having no disorder in the creatine metabolism can be used for preventing the effects of depletion of the muscle phosphoryl creatine store **during intensive activity** and thereby improve the capacity of the muscles, to prevent muscular fatigue and shorten the recovery phase, **or** for **pre-treatment in connection with heart surgery**, to **the treatment of anginose patients, respiratory insufficiency, decreased lung function, emphysema, to a patient in need of oxygen treatment, to patients treated with artificial respiration, postoperative and for general malnutrition, for fibromyalgia and to patients with different types of myopathies in order to increase the acutely available energy depots in muscle tissue with limited capacity of glycolytic or mitochondrial energy production.** According to Sandstedt et al, Clinical Nutrition, Vol. 10, 1991, pages 97-104, see especially page 101, phosphocreatine levels generally are reduced in muscle tissues after they are subjected to **injuries or surgical operations**.
>
> Thus, there has been a demand for a safe and simple preparation which without side effects can be given to mammals suffering from the **above identified insufficiencies** or whose muscular tissue of any reason needs a supply for correct and effective function.
> . . .
> The object of the present invention is to provide a cheap, simple and safe preparation, without side effects which can be given to mammals having no disorders in their creatine metabolism. Said preparation can be used in connection with the **disorders identified above and also** to prevent the effects of depletion of the muscle phosphoryl-creatine store during intensive activity and thereby improve the capacity of the muscles and also shorten the recovery phase.

'159 Patent col. 3 ll.1-28, ll 43-50 (emphasis added). As Judge Orenstein aptly noted "the invention's use for treatment to 'prevent[] the effects of depletion of the muscle phosphoryl creatine store during intensive activity' appears as one of several separately enumerated applications, only a minority of which are related to intense physical activity and most of which clearly concern the invention's medical applications." (R&R at 10.)

The recent decision in *ICU Med., Inc. v. Alaris Med. Sys.*, 558 F.3d 1368 (Fed. Cir. 2009)

is instructive. In *ICU*, the Federal Circuit upheld the district court's construction of the term "spike" as used in the patent at issue therein which construction relied upon the specifications. In reaching this result, the Court stated:

> We have consistently explained that claim terms should generally be given their ordinary and customary meaning and that such meaning is one "that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." . . . Moreover, "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears but in the context of the entire patent, including the specifications.'" This last tenet derives from the fact that claims do not stand alone but rather "are part of a 'fully integrated written instrument,' consisting principally of a specification that concludes with the claims.'"

Id. at 1374 (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005). Although a court "should not import limitations from the specifications into to the claims," the *ICU* Court recognized that "the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court focus remains on understanding how a person of ordinary skill in the art would understand the claim terms . . . after reading the *entire* patent." *Id.* at 1375 (quoting *Philips,* 415 F.3d at 1323 (emphasis added).

Here, to paraphrase the *ICU* Court, the "specification repeatedly and uniformly describes" the invention's medical applications and not just its application related to intense physical activity. *See id.* at 1374. Given that the specification is usually "dispositive" and "is the single best guide to the meaning of a disputed term," *Vitronics*, 90 F.3d at 1582, OCPC's proposed definition must be rejected.

Having considered all the arguments raised by the parties, OCPC's objections are denied

and the Court adopts Judge Orenstein's recommendation, both in reasoning and result, that "suffering from or running a risk of depletion of muscle phosphoryl creatine storage" means "having reduced, or potentially reduced, phosphoryl creatine storage in muscle."

B. "Not less than an amount corresponding to 15 g creatine in a 70 kg mammal"

In its objections to the R&R, MED-Rx contends that the correct construction of "not less than an amount corresponding to 15 g creatine in a 70 kg mammal" is "administering said creatine only to mammals of at least 70 kg body weight, in an amount not less than 15g."

To adopt MED-Rx's position would violate the precepts that "the words of a claim are generally given their ordinary and customary meaning," *Phillips*, 415 F.3d at 1312 (internal quotations omitted), and that "claim construction that gives meaning to all the terms of the claim is preferred over one that does not", *Merck & Co v. Teva Pharms. USA Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005). The claim's use of the term "corresponding to" clearly implies a ratio, as opposed to an absolute amount. Moreover, as Judge Orenstein noted, there is nothing in the specifications that suggests that the term should be construed as other than a ratio; a conclusion that also finds support in the prosecution history. (*See* R&R at 17-21; *see also* '159 Patent col. 1, ll.10-14, 17-19; *id.* col. 3, ll.1-19, 64-66; *id.* col. 4, ll.5-6, 7-8, 15-16.)

Nor is the Court persuaded by MED-Rx's arguments based on the Australian and British patents. As the Federal Circuit has noted: "'the varying legal and procedural requirements for obtaining patent protection in foreign countries might render consideration of certain types of representations inappropriate' for consideration in a claim construction analysis of a United States counterpart." *TI Group Automotive Systems*, *Inc. v. VDO North America, L.L.C.*, 375 F.3d 1126, 1136 (Fed. Cir. 2004) (quoting *Caterpillar Tractor Co. v. Berco. S.p.A.*, 714 F.2d 1110,

1116 (Fed. Cir. 1983)); *see also Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006). MED-Rx's reliance on *Microsoft Corp. v. Multi-Tech. Sys. Inc.*, 357 F.3d 1340, 1349 (Fed. Cir. 2004) for the proposition that "the prosecution history of a related patent is relevant to understanding the scope of a term in common with the patent-in-suit," (MED-Rx Obj. at 17) is not inapposite. In *Microsoft*, the related patents were all U.S. patents.

MED-Rx's objections are denied and the Court adopts Judge Orenstein's reasoning and result as to the construction of "not less than an amount corresponding to 15 g creatine in a 70 kg mammal."

IV. Claim 17 of the '544 Patent

Judge Orenstein recommended that the term "unitary doses" in claim 17 of the '544 Patent be held to mean "10-20 grams of creatine composition that are individually packaged in sachets, bags, packets, cylinders, bottles or other suitable packages." The Court agrees.

Such as construction is consistent with the specifications of the '544 Patent, which provides in relevant part:

> Typically the powder is such that, when a certain amount is dissolved in a pre-determined volume of water, it provides an isotonic drink. **Desirably, the powder is provided as unitary doses (of about 10-20 grams) which may be dissolved in 200-350 mls of water to provide an isotonic drink. The unitary doses are conveniently supplied individually packaged in sachets, bags, packets, cylinders, bottles or other suitable packaging means. Preferably the package is hermetically sealed (e.g. a thin foil sachet) to prevent the ingress of water or water vapour.** In some embodiments it may be desired to provide with the package a volumetric measuring means to allow a user to measure out an appropriate volume of water in which to dissolve the contents of the package. Typically this may take the form of a water-tight container (e.g. of plastics material) with one or more graduations to indicate a certain volume. The container may take

> the form of a beaker or similar vessel, to hold water in which the composition may be dissolved, and from which the resulting solution may be drunk

'544 Patent, col. 3, ll.21 - 39. The construction of "unitary doses" that OCPC objects to is taken directly from the specification, which as noted earlier provide "the single best guide to the meaning of a disputed term," *Vitronics*, 90 F.3d at 1582. OCPC's objections are denied and the Court adopt's Judge Orenstein's reasoning and result with respect to the construction of "unitary doses."

Conclusion

Having conducted a *de novo* review, the Court denies the parties' objections to the R&R and adopts Judge Orenstein's Report and Recommendation in its entirety.

SO ORDERED.

Dated: Central Islip, New York
April 28, 2009

/s/
Denis R. Hurley
Senior District Judge